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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,194	12/01/2003	John Fitzgerald Kokai-Kun	7787.0061-00	1338

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/724,194	KOKAI-KUN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18-25,28, 39-58*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-25,28 and 39-58* is/are pending in the application.

4a) Of the above claim(s) *39-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 18-25, 28, 39-58 are pending.

Claim 18 has have been amended.

Claims 18-25 and 28 are under consideration.

Claims 39-58 remain withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2006 has been entered.

Objections/Rejections Withdrawn

1. ***Claim Objections withdrawn:*** The objection to claims 26-27 and 29-30 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that the claims have been amended to "inhibits or prevents a staphylococcal infection" is withdrawn in light of the cancellation of the claims.

1. ***Claim Rejections - 35 USC § 102 Withdrawn***: The rejection of claims 18-30 under 35 U.S.C. 102(b) as being anticipated by Fischer et al (WO98/57994) as evidenced by (PG Pub 20030228322A1) is herein withdrawn in light of the amendment of claim 18 to be directed to compositions of antibodies specific for ribitol phosphate structure of the wall teichoic acid of S.aureus .

New Grounds of Rejection

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18 , 21-25 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for various compositions that comprise polyclonal antibodies and monoclonal antibodies to ribitol teichoic acid of S.aureus, does not reasonably provide enablement for the specific combinations of monoclonal antibodies which have non-identical amino acid sequences, as well as chimeric, humanize antibodies and ribitol teichoic acid antigen binding fragments thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use novel strains with unobvious characteristics the invention commensurate in scope with these claims.

The claims are directed to a specific monoclonal antibodies produced by a genetically unique hybridoma cell lines, that needs a perfected deposit, as well as deposited strains of S. aureus that serve as a source ribitol teichoic acid antigen for the claimed monoclonal antibodies. For each deposit made pursuant to the Budapest Treaty regulations, shall contain:

(1) The accession number for the deposit;

(2) The date of the deposit;

(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

(e) Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section must be filed before or with the payment of the issue fee (see § 1.312).

[Added, 54 FR 34882, Aug. 22, 1989, effective Jan. 1, 1990; paras. (b) and (c) revised and para. (e) added, 66 FR 21092, Apr. 27, 2001, effective May 29, 2001]

As well as a statement that removes restrictions to provide access to the claimed hybridoma cell lines which expresses the claimed monoclonal/chimeric/humanized antibodies directed to the wall teichoic acid antigen, upon granting of a patent has not made, either in the instant Specification, nor in Applicant's Remarks. One of the critical conditions of Deposit is

defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. Upon making this statement, the rejection under 35 USC 112, first paragraph will be withdrawn. This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 18-19 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorland et al (1998).

Vorland et al disclose a composition of anti-ribitol staphylococcal Teichoic acid antibodies (see materials and methods, page 468, col. 1, Reagents, obtained from Meridian Diagnostics; also see page 470, col. 1, second paragraph; col. 2, paragraph 3 "TA with a poly(ribitol phosphate) chain, in S. aureus"), together with 2% bactopeptone water, an acceptable carrier (see page 468, col. 1, Strains section and col. 2, Blocking experiments "Antibodies to TA (anti-TA) and LTA (anti-LTA) were added to S. aureus "), wherein the antibodies blocked binding of Lf-cin B(see page 470, col. 2, paragraph 6"only antibodies to TA blocked the activity of Lf-cin B" ; see page 471, col. 1, paragraph 2 "we have shown that TA is the initial binding site of Lf-cin B") and served to bind to S. aureus teichoic acid, the teichoic acid being a transport means S.aureus lethal effects (see page 471, col. 2, first paragraph). Antibody binding to S. aureus ribitol teichoic acid would interfere, block S.aureus teichoic acid functions. The anti-ribitol teichoic acid antibody composition of Vorland et al anticipates the instantly claimed invention as now claimed.

6. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by White et al (1983).

White et al disclose the instantly claimed invention directed to compositions of antibodies directed to the ribitol teichoic acid of Staphylococcus aureus (see page 106, paragraph 2, near bottom of paragraph " A **purified antigen or antibody** must be utilized to identify the teichoic acid (TA) line. We and others have run a known **positive antiserum pooled concentrated human gammaglobulin** (Gamma G from Merck Sharp & Dohme, Westpoint, Pennsylvania, USA). We utilized for standardization of the antibody purified **ribitol teichoic acid** prepared by either Dr. G. W.

Ross, Glaxo Laboratories, Greenford, England). White et al found TA antibodies in 12-35% (mean 17%) of sera of uninfected subjects with extracts containing TA concentrations of 1mg/ml but only 0-17% (mean 5%) of sera when TA concentrations were 4mg/ml or higher. These difference were statistically significant ($p < 0.02$).

The anti-ribitol teichoic acid antibody compositions of White et al inherently anticipate the instantly claimed invention directed to compositions of antibodies specific for ribitol teichoic acid of Staphylococcus aureus (see White, page 106, line 3 "S.aureus" and title "staphylococcus". White does not describe all of the functional characteristics of the anti-ribitol teichoic acid antibodies, the functional characteristics of the antibodies directed to the same or equivalent antigen would inherently evidence the same or equivalent functions.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

7. Claims 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Godin et al (1980).

Godin et al disclose composition of antibodies specifically directed to the teichoic acids of Staphylococcus aureus (see abstract, English title, page 296), wherein the antibodies are specific to S. aureus polysaccharide A (see abstract and Table 1, strain S. aureus 263). Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference

between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 18-25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al (US Pat. 6,939,543, filing date June 2001) in view of Patti (US Pat. 6,703,025, filing date August 31, 1999).

Fischer et al teach and show opsonic and protective monoclonal and chimeric antibodies specific to lipoteichoic acids of gram positive bacteria (see title), to include Staphylococcus aureus (see col. 2, line 2), wherein the teichoic acids comprise either glycerol phosphate or ribitol phosphate (see col. 5, lines 32-35). Fischer et al produced anti-glycerol phosphate antibodies and teach that both glycerol phosphate and ribitol phosphate are present in gram positive

Staphylococcus aureus cell walls (see col. 5, lines 32-40) "in general teichoic acids make up a major part of the cell wall" but differs from the instantly claimed invention by failing to show ribitol phosphate antibodies.

Patti et al teach the production of antibodies to glycerol or ribitol phosphate in an analogous art for the purposes of producing anti-teichoic antibodies (see col. 22, lines 48-52) associated with staphylococcal antigens (abstract) to increase the opsonization and phagocytosis of S. aureus (see col. 22, lines 30-35 and 48-52).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the compositions of Fischer et al to include anti-ribitol teichoic acid antibodies in view of the guidance and teaching of Patti et al because Patti et al teach anti-ribitol and anti-glycerol teichoic acid antibodies provide for increase opsonization and phagocytosis of Staphylococcus aureus and Fishcer et al teaches ribitol and glycerol teichoic acids are major antigens in the cell was of gram positive/Staphylococcal pathogens to include Staphylococcus aureus.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining anti-ribitol teichoic acid antibody compositions directed to S. aureus cell wall antigen, because Patti et al teaches that through using ribitol phosphate linked to peptidoglycan, the teichoic acids are antigen and antiteichoic acid antibodies are produced (see col. 22, lines 48-52) and Fischer et al teaches and provides motivation for the production of recombinant antibodies and fragments of anti-ribitol teichoic acid antibodies because the through recombinant means provide for the

generation of vaccines and other therapeutics (see Fischer abstract). Fischer in view of Patti obviated the instantly claimed invention as now claimed.

Conclusion

10. This is a non-final action.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Pat 4954449; 4744982. Nagel et al (1977); Wergeland et al (1989); US006939543B2 and US006610293B1 are cited to show teichoic acids of Staphylococcus.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MARK NAVARRO
PRIMARY EXAMINER